PATENT **DOCKET JB0602**
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
In Re application of J. BANGO ET AL

Examiner:
VARGOT, MATHIEU D.
:Group 1791

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:Date 06/04/08
Attorney Docket: JB0602

Re: The Application For:
FABRICATION OF IMPROVED CONTACT LENS UTILIZING POLYMER ELECTROSPINNING

Declaration In Support Of Patentability Under 37 C.F.R. 1.132

Re: THE FOLLOWING DECLARATION OF GARY E. WNEK

4 June, 2008

DECLARATION AND STATEMENT OOF GARY WNEK:
RELATING TO "Simpson et al publication US No. US 2002/0090725,
PUBLISHED ON July 11, 2002

I, Dr. Gary Wnek, do hereby say and declare: This is my statement relating to my review of a prior art patent reference on which I am listed as a co-inventor, and which is cited by patent examiner Niebauer, as that reference relates to pending patent application number 10/414,796.

My qualifications for making the following declaration:

Past and Present Employment:

GARY E. WNEK
Joseph F. Toot, Jr., Professor of Engineering
Chair, Department of Macromolecular Science and Engineering
Faculty Director, The Institute for Management and Engineering (TiME)
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Former Positions

Advisory Board, Department of Chemical Engineering, Worcester Polytechnic Institute, 1990-; Chair, 2003-
Research Interests
Polymers with unusual electrical or optical properties
Ironically conducting polymers with applications in fuel cells and batteries
Electro active polymers in medicine and biotechnology
Electric field-mediated phenomena: electrostatic polymer processing of nano- and micro fibers and particles; morphology modulation in polymer blends; modulation of optical properties of polymers. Biomaterials for tissue engineering and regenerative medicine
New polymer-based micro fluidic platforms

Date(s) Of Review: 15 August 2007
Prior Art References: Electro processed Collagen, David Simpson et al, US No. US 2002/0090725

I have been engaged in polymer research for nearly 30 years and with electrospinning of polymers for over 10 years.

Ph.D., Polymer Science and Engineering, University of Massachusetts, Amherst, 1980 Thesis Advisor: Dr. James C. W. Chien
Date and Place of Birth
September 9, 1955; Amsterdam, NY
Publications (See Appendix for complete list)
Over 130 papers and book chapters; 18 US patents.
Awards and Honors
Kern Faculty Fellow, Kern Entrepreneurship Education Network, 2006-07
Honorary Member, Golden Key International Honor Society, 2005-
NASA Lecturer, 64th Frontiers in Chemistry Symposium, Case Western Reserve University, 2004 Sidney Negus Memorial Lecturer, Virginia Academy of Sciences, 1999
1996 Eastern New York Intellectual Property Law Association Inventor of the Year Award (for U.S. patent 5,468,574)
Union Carbide Lecturer, 44th Frontiers in Chemistry Symposium, Case Western Reserve University, 1985 Lecturer, Whitney Symposium on Science and Technology, General Electric CR&D, 1985 ARCO Career Development Award, 1985-1987
IBM Faculty Development Award, 1983-1985
Dupont Young Faculty Award, 1980-1983
Professional Societies
American Chemical Society (Divisions of Polymer Chemistry and Polymeric Materials: Science and Engineering)
American Institute of Chemical Engineers
Materials Research Society
Electrochemical Society
Product Development Management Association
Professional Activities
Co-Editor, Encyclopedia of Biomaterials and Biomedical Engineering (Marcel Dekker), 2004-Councilor, ACS Division of Polymer Chemistry, 2005-2007
Board of Consulting Editors, McGraw-Hill Encyclopedia of Science and Technology and Yearbook of Science and Technology, 2002-2004
Member, Panel on Organic and Hybrid Materials, Materials Research for Defense-After-Next, National Materials Advisory Board, 200 1-2002
Scientific Advisory Board, GliaMed, Inc., Bronx, NY, 2003-
Scientific Advisory Board, Bio-Track LLC, Richmond, VA, 200 1-
Scientific Advisory Board, Energy Voyager Inc., Santa Barbara, CA, 2005-
Associate Editor, Chemistry of Materials, 1989-1996
Editorial Board, Chemistry of Materials, 1997-2000
Editorial Board, Polymer-Plastics Technology and Engineering, 1998-
Editorial Board, Progress in Polymer Science, 1993-95
Co-Founder, Dais Corp., 1993 (now Dais Analytic Corp.)
Co-Founder and CSO, Aegis BioSciences LLC, 1996-
Co-Founding Inventor, NanoMatrix, Inc., 2000-
Co-Principal, Class Express LLC, 2004-

The examiner makes reference to a corona discharge as an ion source to mitigate fiber instability. A corona is in effect a plasma, and as such over a thousand of degrees F in temperature. Such high temperature might denature collagen.

Use of a plasma produces ozone, which might further destabilize collagen. As such, I would not see a corona as being an enabling means to minimize fiber spinning instability for this application.

Finally, the examiner cites the use of the microprocessor in the spinning operation. The microprocessor was used in the process taught in Simpson to direct the angle and distance and voltage of the tip of the needle with respect to the target, depending on the desired fiber morphology and deposition required for a given application.

The microprocessor commanded a fixed voltage once our process was activated.

The microprocessor in the Simpson process was not used to deliver an AC rather than DC potential to the electrospinning source and target. The mats produced were contemplated to be as structurally sound as we could make. We did not contemplate making an optically clear mat.

As a result of not contemplating the need to make an optically clear mat, we were never faced with the problems associated making micro fibers and forming a fiber matrix that would be optically clear. We were ~~not~~ aware of the problem with hydrodynamic instability but because we were making fiber with a larger diameter than those characterized in the subject application, the need for formatting a matrix aperture having optical clarity was not an area of investigation that we thought of, or that we intended to pursue.

I am currently Chair of Macromolecular Science and Engineering at Case Western Reserve University in Ohio. I was a principal Investigator at Virginia Commonwealth University in the electrospinning, henceforth electro-processing, program at VCU which resulted in the cited patent reference US No. 2002/0090725 to Simpson et al. I am a co-inventor on that application.

The purpose of our research which was subsequently reported in the literature and documented in the cited patent reference, was to produce a biomimetic tissue scaffold suitable for, and to encourage, cellular in growth and neovascularization. Our team had no interest in and to my knowledge never thought about removing the charge from the electrospun fibers as the electrohydrodynamic instability cited in the Bango application does not present itself as a problem in the application of tissue scaffolds. In our work, we had no interest in making electrospun collagen fibers optically clear. Optical clarity in the visible spectrum requires mimicking the fibril diameter and mean fibril spacing exhibited by native tissue, specifically under 100 nanometers in diameter. We rarely if ever spun fibers under 100 nanometers. The diameter of the individual fibers in the cited Simpson et al. application was to be larger than those in the Bango et al. application.

I consider the use of AC or alternating current for mitigating spray instability the electrospray source to be novel. The need for AC voltage was not necessary nor contemplated for the scaffolding application taught in the Simpson publication.

Ultraviolet light and/or radiation was used in the process taught in the Simpson publication to promote polymer crosslinking or fiber sterilization. Ultraviolet light was not used in the Simpson process taught in the Simpson publication to remove any charge buildup on the spun fiber.

I hereby declare that all statements made herein of my own know edge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the know edge that statements, and the like, so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such false statements may jeopardize the validity of the application or any patent issued thereon.

Given Name (first and middle [if any]) GARY E

Family Name or Surname WNEK

Inventors Signature:

Date:

Residence City Cleveland

State Ohio

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Citizenship U.S.

Mailing Address Case Western Reserve University
Joseph F. Toot, Jr., Professor of Engineering
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APPENDIX
Authored and Co-Authored Publications (130)

E. Karasz, J. C. W. Chien, R. Galkiewicz, G. E. Wnek, A. J. Heeger and A. G. MacDiarmid, "Nascent Morphology of Polyacetylene," Nature, 282, 286 (1979).
E. Wnek, J. C. W. Chien, F. E. Karasz, M. A. Druy, A. G. MacDiarmid, Y. W. Park and A. J. Heeger, "Variable Density Conducting Polymers: Conductivity and

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J. C. W. Chien, F. E. Karasz and G. E. Wnek, "Soliton Formation and Cis-Trans Isomerization in Polyacetylene," Nature, 285, 391 (1980).
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G. E. Wnek, J. Capistran, J. C. W. Chien, L. C. Dickinson, R. Gable, R. Gooding, K. Gourley, F. E. Karasz, C. P. Lillya and K. D. Yao, "Studies in Conducting Polymers," in Conductive Polymers, Polym. Sci. & Tech. Ser., Vol. 15, R. B. Seymour, ed., Plenum, 183 (1981).
J. C. W. Chien, G. E. Wnek, F. E. Karasz, J. M. Warakomski, L. C. Dickinson, A. J. Heeger and A. G. MacDiarmid, "Electron Paramagnetic Resonance Saturation Characteristics of Pristine and Doped Polyacetylenes," Macromolecules, 15, 614 (1982).
M. E. Galvin and G. E. Wnek, "Electrically Conductive Polymer Composites: Polymerization of Acetylene in Polyethylene" Polym. Comm., 23, 795 (1982).
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A. Guiseppi-Elie and G. E. Wnek, "Stabilization of Iodine-Doped Polyacetylene in Aqueous Solutions," J. Chem. Soc. Chem. Comm., 63 (1983).
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D. R. Uhlmann, B. J. J. Zielinski and G. E. Wnek, "The Ceramist as Chemist - Opportunities for New Materials," in Better Ceramics Through Chemistry, C. J. Brinker, D. E. Clark and D. R. Ulrich, eds., MRS Symp. Vol. 32, Elsevier, North Holland, 59 (1984).
M. E. Galvin and G. E. Wnek, "Towards the Synthesis of Electroactive Block Copolymers via Anionic-to-Ziegler-Natta Transformation Reactions. 2. Evidence for the Formation of Styrene/Acetylene Diblock Copolymers," Polym. Bull., 13, 109 (1985).
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G. E. Wnek, B. Wasserman, M. S. Dresselhaus, S. E. Tunney and J. K. Stille, "Ion Implantation of a Polyquinoline," J. Polym. Sci. Polym. Lett. Ed., 23, 609 (1985).
Wasserman, M. S. Dresselhaus, G. Braunstein, G. E. Wnek and G. Roth, "Electron Spin Resonance Study of Ion-Implanted Polymers," J. Electron. Mater. 14(2), 157 (1985).
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G. Venugopal, S. Krause and G. E. Wnek, "Modification of Polymer Blend Morphology Using Electric Fields," J. Polym. Sci. Polym. Lett. Ed., 27, 497 (1989).
C.-Y. Yang and G. E. Wnek, "Synthesis of Polysiloxanes Bearing Polar Groups," Polym. Prepr., 30(2), 177 (1989).
P. Kitipichai, R. LaPeruta, G. M. Korenowski, G. E. Wnek, I. Gorodisher and D. R. Uhlmann, "New Polymers for Second Harmonic Generation," Polym. Prepr., 30(2), 176 (1989).

F. McDonald, N. P. Vlannes, G. E. Wnek and T.-M. Lu, "Dielectric, Conducting and Photonic Polymers for Devices in Multichip Packaging," Mat. Res. Soc. Proc., Vol. 154, 387 (1989).

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G. Venugopal, S. Krause and G. E. Wnek, "The Effects of Electric Fields on Polymer Blend Morphologies," Polym. Prepr., 31(1), 377 (1990).
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J. M. Serpico, G. E. Wnek, S. Krause, T. W. Smith, D. J. Luca and A. Van Laeken, "Electric Field-Induced Morphologies in Diblock Copolymer Containing Polymer Blends,"Polym. Prepr., 33(1), 463 (1992).
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D. B. O'Connor, G. W. Scott, K. Tran, D. R. Coulter, V. M. Miskowski, A. E. Stiegman and G. E. Wnek, "The Low-Energy, Charge-Transfer Excited States of 4-Amino-4'-Nitrodiphenyl Sulfide," J. Chem. Phys., 97, 4018 (1992).
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Z. Zhu, C. Y. Yang, A. G. Einset, W.-X. Chen and G. E. Wnek, "Synthesis of Polysiloxanes Bearing Cyclic Carbonate Side Chains. Dielectric Properties and Ionic Conductivities of Lithium Triflate Complexes ,"Macromolecules., 27, 4076 (1994).
P. Caglar and G. E. Wnek, "Glucose-Sensitive Polypyrrole/Poly(Styrenesulfonate) Films Containing Co-Immobilized Glucose Oxidase and (Ferrocenylmethyl) Trimethylammonium Bromide," J. Macromol. Sci. Pure Appl. Chem., A32, 349 (1995).

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P. Lam, P. R. Elliker, G. E. Wnek and T. M. Przybycien, "Towards An Electrochemically Modulated Chromatographic Stationary Phase," J. Chromatog. A, 707, 29 (1995).

A. G. Einset and G. E. Wnek, "Polymer Electrolyte Review," in Handbook of Solid State Batteries and Capacitors, M. Z. A. Munshi, ed., World Scientific, Singapore (1995).
G. E. Wnek, J. N. Rider, J. M. Serpico, A. G. Einset, S. G. Ehrenberg and L. Raboin, "New Hydrocarbon Proton Exchange Membranes Based on Sulfonated Styrene-Ethylene/Butylene-Styrene Triblock Copolymers," Proc. First Int'l Symposium on Proton Conducting Membrane Fuel Cells, Electrochemical Society Proc. Vol. 95-23, 247 (1995).
D. J. Trantolo, J. D. Gresser, D. L. Wise, M. G. Mogul, T. M. Cooper and G. E. Wnek, "Electric Field Alignment of Biopolymers for Nonlinear Optical Applications," in Optical and Photonic Apllications of Electroactive and Conducting Polymers, SPIE Proc. Vol. 2528, 219 (1995).
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"Polymer Nanofibers by Electrospinning and Applications in Medicine," Symposium on Nanotechnology and Education, ACS Meeting, Anaheim, CA, March 29, 2004.
"Electrostatic Polymer Processing: Applications to Biomaterials and Electrochemical Devices," Dept. of Polymer Engineering, University of Akron, April 9, 2004.
"Electrostatic Polymer Processing of PEMFC Components," Gordon Research Conference on Fuel Cells, Roger Williams University, Bristol, RI, July 29, 2004.
"Polymer Engineering for Energy Conversion Technologies," Frontiers in Chemistry Series, Case Western Reserve University, October 28, 2004.
"Nanomaterials for Fuel Cells," PolymerOhio Emerging Technology Forum, Case Western Reserve University, November 17, 2004.
"Electrostatic Polymer Processing Applied to PEMFC Fabrication," ACS workshop on New Advances in Proton Exchange Membrane Fuel Cells, Asilomar, CA, February 23, 2005.
"Medical Applications of Electrostatic Polymer Processing," Guidant Corporation, Santa Clara, CA, February 23, 2005.
"Polymer Engineering for Energy Conversion Technologies," Golden Gate Polymer Forum, Mountain View, CA, February 23, 2005.
"Structure-Property Relationships in Biopolymers," ACS short course on Polymers in Medicine, Richmond, VA, June 8, 2005.
"Electrostatic Polymer Processing Applied to PEMFC Fabrication," 1st Symposium on Manufacturing of MEAs for Hydrogen Applications, Dayton, Ohio, August 10, 2005.
"Nanomaterials with Applications to Medicine and Energy," Materials Science and Engineering Alan Lawley Seminar, Drexel University, Philadelphia, November 1, 2005.
"Electrostatic Polymer Processing Applied to PEMFC Fabrication," Pacific Polymer Conference, Maui, HI, December 12, 2005.

"Nanomaterials with Applications to Medicine and Energy," Materials Engineering colloquium, Purdue University, W. Lafayette, IN, March 3, 2006.

"Applying TRIZ Methodology to Innovation Strategy," Ohio Polymer Summit, Columbus, May 23, 2006 (with Zion Bar-El).
"Nanomaterials with Applications to Medicine and Energy," Dow Discussion Group on Interface Science, Dow Chemical Co., Midland, MI, May 24, 2006.
"Electrospinning of Polymers: Fundamentals and Medical Applications," International Conference on Polymer Chemistry, Dalian, China, June 10, 2006.
"Electrospinning of Polymers: Fundamentals and Medical Applications," Mini-Symposium on Functional Polymers and Nanostructured Materials for Biotechnology and Medicine, Shanghai Jiao Tong University, Shanghai, China, June 12, 2006.
Short Courses
"Practical Polymer Science," Denison Manufacturing Co., Framingham, MA, February-March 1981 and May 1986.
"Electrical Properties of Polymers," one-week summer course, MIT, Cambridge, MA, 1985-1989.
"Electrically Conducting Polymers," ACS Satellite TV Course, Washington, DC, March 16, 1990 (with P. D. Calvert and D. J. Meier).
"Polymer Chemistry," three-day short course for college faculty, Temple University, Philadelphia, March 29-31, 1990.
"Chemistry and Materials Science," NSF Chautauqua Course for College Teachers, U. of Pittsburgh, June 16-18, 1994.
"Chemistry and Materials Science," NSF-UFE Short Course, Bucknell U., Lewisburg, PA, August 4-6, 1994.
"Polymer Chemistry for University Faculty," NSF-supported, 3-week summer course at RPI (G. E. Wnek, P.I., with S. Krause and J. A. Moore), 1989, 1991, 1993 and 1996.
"Essentials of Polymer Chemistry," ACS Satellite TV Course, Washington, DC, March 23 and 25, 1998 (with J. E. McGrath, K. J. Wynne and D. A. Tirrell; organized by G. E. Wnek).
"Polymers in Medicine: Principles and Practice," ACS short course held at VCU, June 2003; organized by K. J. Wynne, co-organized by G. E. Wnek.
"Polymers and Bio-Polymers in Medicine," Golden Gate Polymer Forum Short Course, May 5-7, 2006 (co-organized co-taught with Allan Hoffman and Stuart Williams).

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